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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/578,224	05/24/2000	Thomas Schwalbe	CELL0013	4618

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EXAMINER	
LEUNG, JENNIFER A	

ART UNIT	PAPER NUMBER
1764	14

DATE MAILED: 10/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/578,224	SCHWALBE ET AL.	
	Examiner	Art Unit	
	Jennifer A. Leung	1764	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,16-26 and 71-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,16-26 and 71-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☒ The proposed drawing correction filed on *16 July 2003* is: a)☒ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Amendment

1. Applicant's amendment submitted on July 16, 2003 has been received and carefully considered. The changes made to Drawings are acceptable. Claims 15 and 27-70 have been cancelled. Claims 72-74 have been added. Claims 1-14, 16-26 and 71-74 remain active.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The language of the claim is directed towards a process limitation which renders the claim vague and indefinite, as it is unclear as to the structural limitation applicants are attempting to recite, since "a quantity of said chemical product produced by the modular system" (lines 1-2) is not considered an element of the apparatus. Applicants' argument against the rejection of the claim's use of "functional limitations" (page 10, line 28 to page 11, line 2) is not persuasive, since the functional limitations recited in at least one of (a), (b) and (c) are process limitations for increasing the quantity of chemical product produced by the modular system. Furthermore, providing "a different pump module having an increased flow rate", "a different reactor... to provide an increased rate of production," and "a different reaction module... to provide an increased rate of production," provide no further structural limitation but constitute intended use recitations, which hold no patentable weight in apparatus claims, since "flow rate" and "rate of production" are not considered elements of the apparatus.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1, 3-5, 9-14, 18, 20-26, 71, 72 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bard (U.S. 5,580,523) in view of Dewitt et al. (EP 0 796 654) OR Agrafiotis et al. (U.S. 5,463,564).

Regarding claims 1 and 71, Bard (FIG. 2, 3, 4; generally, column 4, lines 21 - column 5, line 18 and column 6, line 66 - column 7, line 20) discloses a modular system for synthesizing a variety of chemical products, comprising:

(a) a control module, being adapted to monitor and automatically control the production of a chemical product in the modular system (i.e., an interface **90** for communicating with a master control center or computer -- which is *inherently* a processor. Note that reference **90** is unlabeled in FIG. 4);

(b) a reactant supply source **A**, **B** for a plurality of reactants, a flow of each reactant from its reactant supply source being controlled by the control module; and

(c) a first reaction module in fluid communication with at least one reactant supply source **A**, **B** to receive at least one of the plurality of reactants, the first reaction module being controllably connected to the control module and including a replaceable reactor **R** (i.e.

configured as a detachable and interchangeable reaction chip type unit; column 2, lines 32-47; column 4, lines 53-64), wherein reactor **R** automatically produces the chemical product from the plurality of reactants **A**, **B** under the control of the control module. In view of the newly added limitations, Bard is silent as to the control module comprising a reaction database, such that a user may interact with interface **90** to select a specific reaction to produce the chemical product from a plurality of reactions stored in the reaction database.

Dewitt et al. teach a system for developing and performing multiple simultaneous syntheses utilizing a reactor or synthesis apparatus **28** (FIG. 1a), wherein the system includes a control module (FIG. 1) comprising a processor (information management system module **12**), a reaction database **72**, and a user interface (column 7, lines 33-46). The control module is configured to enable a user to interact with the interface to select a specific reaction to produce a desired chemical product from a plurality of reactions stored in the reaction database **72**, so that in response to a selection made by a user (FIG. 5; column 10, lines 18-34), the processor automatically controls the apparatus **28** to produce the chemical product according to stored reaction parameters for the specific product selected (column 6, line 37 to column 7, line 4).

Additionally, Agrafiotis et al. (FIG. 1, 2, 11) teach a computer-based system for iteratively generating chemical entities utilizing apparatus such as the Chemical Synthesis Robot **112** (column 7, lines 34-44; column 8, line 22 to column 9, line 38), wherein the system includes a control module comprising a processor **106** (column 7, lines 48-55), a reaction database (for synthesizing the Directed Diversity Chemical Library **208** using stored Structure-Activity Data **210** and Historical Structure-Activity Data **212**; column 7, lines 5-27) and a user interface (input devices **121**; column 8, lines 7-14). The control module enables a user to interact via interface

121 to select a specific reaction to produce a desired chemical product (lead compound **216**) from a plurality of stored reactions, so that in response to a selection made by a user, the processor **106** automatically controls the Synthesis Robot **112** (via logic **108**) to produce the product **216** according to the stored reaction parameters (synthesis instructions **204**).

It would have been obvious for one of ordinary skill in the art at the time the invention was made to provide a control module having a reaction database for the control module in the apparatus of Bard et al. because the reaction database, when incorporated with an information management system (i.e., a processor) and a user interface, enables automatic selection and distribution of reagents and processing steps that are to be sequentially provided at each reaction vessel, depending on the desired product structure selected by the user, as taught by Dewitt et al. (column 3, lines 20-56). Additionally, a reaction database provides a means for the storage of chemical property data from previously synthesized compounds, thereby enabling the iterative generation of directed, new synthesis instructions for controlling future chemical compound synthesis, as taught by Agrafiotis et al. (column 3, line 28 to column 4, line 16).

Regarding claim 3, Bard discloses the apparatus is particularly applicable for the synthesis of compounds under extreme conditions, such as supercritical temperatures and pressures (column 3, lines 24-30, 53-58). Supercritical fluids exhibit properties much like that of gases, and thus the apparatus is *inherently* capable of accommodating a gaseous reactant.

Regarding claim 4, Bard discloses a pump module (comprising pumps $\mathbf{P_A}$, $\mathbf{P_B}$) controllably connected to the control module (via signal **P**) and in fluid communication with each reactant supply source **A**, **B** and with said first reaction module, the pump module pumping at least one fluid **A**, **B** through the modular system (FIG. 4; column 7, lines 9-20).

Regarding claims 5 and 9-10, Bard discloses an additional processing module may be placed in fluid communication with the first reaction module and comprise a second reaction module, wherein the additional processing module is controllably connected to the control module and includes a reactor (i.e., a reactor **R**), so that the apparatus produces the chemical product using a plurality of synthesis steps, a first synthesis step being completed in the first reaction module and a second synthesis step being completed in the second reaction module. This reads on Bard's, "serial placement of reactors to allow controlled sequential reactions of intermediates," and "a plurality of individual, detachable reaction units," wherein, "one of the reaction units may be structurally different and capable of permitting a different chemical process of being performed," (column 2, lines 32-47 and 61-67; column 4, lines 53-58).

Regarding claim 11, Bard discloses reactor **R** configured for producing a class of chemical products (i.e., classes synthesized by either "thermal, electrochemical, catalytic, enzymatic, photochemical, or hollow chamber type" reactors; column 2, lines 32-47; column 4, lines 53-64), and is selectively readily removable from the first reaction module and replaceable with a different reactor **R** configured for production of a different class of chemical products.

Regarding claim 12, Bard discloses a key aspect of the invention is to "provide an Integrated Chemical Synthesizer (ICS) system that is modular in design," wherein, "[t]he modular nature of the system, component parts, e.g. the reactors, flow channels... allows easy replacement and/or interchangeability of the component parts," (column 2, lines 32-47). Bard discloses that to provide such ease, the component parts may comprise a housing (i.e. illustrated as a chip unit **100**; FIG. 1d, 2, 3), wherein housing **100** comprises a first side having a port **10** and a second side having a port **11**, enabling communication with the reactant supply and

additional processing modules. Bard also discloses housing **100**, which defines the replaceable reactor **R**, is removably connected to the other system components via mounting/dismounting from mounting frame or assembly board **20** (column 6, lines 26-33). Regarding the provision of a plurality of ports, it would have been an obvious design choice for one of ordinary skill in the art at the time the invention was made to provide a plurality of ports for the port of the apparatus of Bard, on the basis of suitability for the intended use (i.e., for enabling feed of plural reactants **A, B** individually), since duplication of part was held to have been obvious. *St. Regis Paper Co. v. Beemis Co. Inc.* 193 USPQ 8, 11 (1977); *In re Harza* 124 USPQ 378 (CCPA 1960).

Regarding claims 13-14, Bard (column 7, lines 1-20) discloses the first reaction module comprises means for facilitating production of the chemical product, wherein said means comprises a heat exchanger (a "heat transfer system" illustrated as **H** in FIG. 4, not labeled in the specification) and a temperature sensor (a thermocouple **TC**).

Regarding claim 18, Bard discloses the pump module comprises at least one pump $\mathbf{P_A}$, $\mathbf{P_B}$ controllably connected to the control module to control its operation (FIG. 4; column 4, lines 35-37; column 7, lines 9-20).

Regarding claims 20-21, Bard discloses at least one pump $\mathbf{P_A}$, $\mathbf{P_B}$ in fluid communication with both the reactant supply source and the first reaction module, wherein a separate pump is provided for each of the plurality of reactants **A, B** for communication with the first reaction module (pump $\mathbf{P_A}$ for source **A**; pump $\mathbf{P_B}$ for source **B**; FIG. 4).

Regarding claim 22, Bard discloses the pump module comprises at least one valve ($\mathbf{V_A}$, $\mathbf{V_B}$), being controllably connected to the control module (via signal **V**) to control a flow of reactants **A, B** to the first reaction module (FIG. 4; column 7, lines 9-20).

Regarding claim 23, Bard discloses the modular system may comprise separatory components for performing a desired chemical process, and further illustrates the desired chemical process of penicillin fermentation, wherein the pump module comprises filter banks **502**, **503**, for filtering material from Benzylpenicillin (BP) before the BP flows to the reaction module (FIG. 8; column 4, lines 21-29, 46-52; column 6, lines 34-40; column 8, lines 35-67).

Regarding claim 24, Bard discloses, "flow control components that make-up the ICS system can include pumps," and "[t]hese components will have the necessary fittings that allow them to be sealed with the pre-arranged or selectively located flow channels or connectors," (column 4, lines 35-41). However, Bard is silent as to whether the pump module (comprising $\mathbf{P_A}$, $\mathbf{P_B}$) may comprise a housing having a plurality of ports on a first and second side to enable the pump module to be controllably connected to the control module and in fluid communication with the reactant supply source **A**, **B** and first reaction module. In any event, it would have been an obvious design choice for one of ordinary skill in the art at the time the invention was made to provide such for the pump module in the apparatus of Bard, on the basis of suitability for the intended use and absent showing any unexpected results thereof, because provision of a housing and a plurality of ports for the pump module would enable easy replacement and/or interchangeability of component parts as a single unit (i.e., for ease in sealing the components with the pre-arranged or selectively located flow channels or connectors), as evidenced by the provision of a housing and ports to the reaction module of Bard, as discussed in claim 12 above.

Regarding claim 25, Bard discloses the quantity of chemical product produced may be increased by replacing the replaceable reactor in the first reaction module with a different replaceable reactor configured to provide an increased rate of production of the chemical product

(i.e., which reads on providing a reaction chamber of a desired volume, column 5, lines 28-31).

Regarding claim 26, Bard (FIG. 2, 3; column 4, lines 30-36; column 6, lines 26-33) discloses the modules may be fastened together for easy replacement and/or interchangeability using quick connect connectors (i.e. pins **30-37** or clips).

Regarding claims 72 and 74, Bard discloses the replaceable reactor **R** may comprise a microreactor (column 1, lines 7-10; column 3, lines 31-36).

4. Claims 2 and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bard (U.S. 5,580,523) in view of Dewitt et al. (EP 0 796 654) OR Agrafiotis et al. (U.S. 5,463,564), as applied to claims 1, 71 and 72 above, and further in view of Dugan (U.S. 5,658,537).

Regarding claims 2 and 73, (FIG. 4; column 7, lines 1-20) reactor **R** *inherently* defines a reaction volume. Also, Bard discloses a mixer **Mx**, which *inherently* defines a mixing volume, upstream of reactor **R**. However, Bard is silent as to whether the reactor **R** volume and the mixer **Mx** volume may be configured integrally such that reactor **R** comprises both mixing and reaction volumes. In any event, it would have been an obvious design choice for one of ordinary skill in the art at the time the invention was made to configure the reactor **R** in the apparatus of Bard to comprise both a mixing and a reaction volume, on the basis of suitability for the intended use and absent showing any unexpected results thereof, since making elements integral involves ordinary skill in the art. Also, such a configuration is known in the art, as evidenced by Dugan, who teaches a plate-type chemical reactor comprising both a reaction volume and a mixing volume, defined by a static mixing means incorporated into the reactor (Abstract; column 2, lines 16-68; column 3, lines 1-13). The integration of the mixing means with the reactor allows improved temperature control over the mixing process, as taught by Dugan.

5. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bard (U.S. 5,580,523) in view of Dewitt et al. (EP 0 796 654) OR Agrafiotis et al. (U.S. 5,463,564), as applied to claims 1 and 5 above, and further in view of Ghosh et al. (U.S. 5,961,932).

Regarding claims 6-7, Bard discloses a chamber having an I.D. of up to 100 μm to optimize the control of *residence time* within a reaction zone, thereby comprising a "residence time module" by definition (Abstract; column 3, lines 31-36). The chamber may be formed by etching a preformed pattern of a desired volume onto a substrate (column 5, lines 28-31; generally in lines 1-18), wherein the pattern inherently comprises a capillary, as characterized by its small internal diameter. Bard is silent as to whether the volume of the preformed pattern may be varied by selecting a capillary of a given length to obtain a predetermined amount of residence time for the chemical product. Ghosh et al. teach a chemical reactor comprising a chamber **34** which can be made longer by configuring serpentine, complex, wavy, winding and angular forms to allow for longer reaction time (column 5, lines 15-19). It would have been an obvious design choice for one of ordinary skill in the art at the time the invention was made to modify the module of Bard such that it comprised a capillary of an appropriate length to obtain a predetermined residence time for the reaction, on the basis of suitability for the intended use and absent showing unexpected results thereof, since such would allow for the reaction chamber to be designed specifically for a given reaction or reagent/product. Furthermore, it has been held that changes in size involve only ordinary skill in the art. *In re Rose*, 220 F.2d 459, 463, 105 USPQ 237, 240 (CCPA 1955), and where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art, *In re Aller, 105 USPQ 233.*

Regarding claim 8, Bard discloses the, "system provides for uniform temperature control for continuous flow reactors under *elevated pressures*. This allows for precise control of *residence time* within a reaction zone." (column 2, lines 48-51). Bard further discloses, "flow control components that make-up the ICS system can include pumps, flow channels, manifolds, flow restrictor, *valves*, etc." (column 4, lines 36-37). Therefore, the provision of a proportional valve for the residence time module, controllably connected to the control module to selectively vary a pressure within the modular system, would be inherent of the apparatus of Bard, in order to enable the regulation of the recited elevated pressures (see also, column 3, lines 54-59).

6. Claims 16, 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bard (U.S. 5,580,523) in view of Dewitt et al. (EP 0 796 654) OR Agrafiotis et al. (U.S. 5,463,564), as applied to claim 1 above, and further in view of Ashmead et al. (U.S. 5,534,328).

Regarding claim 16-17 and 19, Bard (FIG. 1d, 3) discloses a plurality of fluid paths (i.e. channels **10**, **11**, **81**, **82**, **83**, **84**), including a fluid path for each of the plurality of reactants (i.e. reactants **A**, **B**, flowing into channels **81, 10**; also illustrated in FIG. 4), and a fluid path for the product (i.e. intermediate products flowing through channels **11** and **82** or **83**; final product flowing out of the modular system, via channels **11**, **84**). Bard further discloses a heat transfer system (i.e. illustrated as **H** in FIG. 4; column 7, lines 1-20). However, Bard is silent as to whether the heat transfer system may comprise at least one fluid path for a heat transfer media and at least one fluid path for a spent heat transfer media, wherein the fluid paths are configured in one of a parallel fluidic system and a serial fluidic system, and wherein at least one pump is provided in fluid communication with both a heat transfer media fluid supply and the first reaction module. In any event, it would have been an obvious design choice for one of ordinary

skill in the art at the time the invention was made to select such a configuration for the heat transfer system of Bard, on the basis of suitability for the intended use and absent showing any unexpected results thereof, since substitution of known equivalent structures involves only ordinary skill in the art. *In re Fout* 213 USPQ 532 (CCPA 1982); *In re Susi* 169 USPQ 423 (CCPA 1971); *In re Siebentritt* 152 USPQ 618 (CCPA 1967); *In re Ruff* 118 USPQ 343 (CCPA 1958). Furthermore, such heat transfer systems (i.e. systems comprising flowing, fluid heat transfer media) are conventionally known in the art, as evidenced by Ashmead et al. (FIG. 3, 10; column 2, lines 4-17; column 11, line 66 to column 12, line 15) who teach a reaction module comprising a heat exchanger **74**, wherein the heat exchanger comprises at least one fluid path for a heat transfer media (i.e. via inlet port **75** and flow channels **74C**) and at least one fluid path for a spent heat transfer media (i.e. via channels **74C** and outlet port **76**), wherein the fluid paths are configured in a parallel fluidic system (i.e. parallel pathways for channels **74C**, divided by **77-1**, **77-2**). Ashmead et al. further teach that external flow control means (not shown) may be used for controlling the temperature of the heat exchanger **74**, wherein such external flow control means may comprise a heat transfer media fluid supply (i.e. "a water bath") and known control devices, such as "pumps" (column 7, lines 28-47).

Response to Arguments

7. Applicant's arguments with respect to the rejection of claims 1, 3-5, 9, 10, 13, 14, 18, 20, 22, 25 and 71 under 35 U.S.C. 102(b) as being anticipated by Chaussonnet have been fully considered and are persuasive. Therefore, said rejection has been withdrawn.

8. Applicants' arguments regarding the rejection of claims 2 and 73 under 35 U.S.C. 103(a) as being upatentable over Dugan, as a secondary reference, have been fully considered but are

not persuasive. Applicants assert,

> "... the reactor designs disclosed by Dugan and Bard are so radically different, it does not appear that modifying Bard's reactor to include Dugan's mixing volume is a simple modification, and clearly, such a modification is NOT simply a matter of design. Bard's reactor is disclosed as a volume having an inlet and an outlet, preferably formed using photolithographic or injection molding techniques, neither of which are applicable to produce Dugan's stacked plate reactor. " (Page 13, lines 10-18).

However, the Examiner respectfully disagrees and contends that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In the instant case, Dugan is merely provided to illustrate the inventive concept of providing a reactor and mixing volume in a single housing.

9. Applicants' arguments regarding the rejection of claims 6-8 under 35 U.S.C. 103(a) as being upatentable over Ghosh, as a secondary reference, have been fully considered but are not persuasive. Applicants assert (page 14, lines 1-14),

> "... Bard discloses manipulating the size of the reaction module to control residence time, which is distinctly different than using a separate module (i.e., a reactor) for initiating a reaction, and yet another module for providing sufficient residence time. Bard teaches that sufficient residence time is achieved by changing the design of a reactor -- not by adding a separate module."
>
> "The combination suggested by the Examiner does not enable residence times to be varied without changing the reactor, while the claimed invention can use same reactor and change the residence time by replacing the residence time module."

The Examiner respectfully disagrees with Applicant. In particular, Bard discloses, "The ICS system can include *a plurality of individual detachable reaction units*. With a plurality of units,

one of the reaction units may be structurally different and capable of permitting a different chemical process of being performed," (with emphasis added; column 4, lines 51-64). Also, as commented above, Bard discloses the modules may each comprise an I.D. of up to 100 μm to optimize the control of *residence time* within a reaction zone. Therefore, each of the plurality of individual detachable reaction units comprises a "residence time module" by definition (Abstract; column 3, lines 31-36). Such a configuration *inherently* enables the residence time of a given reactor to be varied without changing the reactor itself, since a second of the plurality of individual detachable reaction units may be changed instead.

Additionally, regarding claim 8, applicants assert (page 14, line 26 to page 15, line 4),

> "There is simply no teaching or suggestion in Bard of disposing a proportional valve downstream of a reactor to control pressure conditions in the system."

The Examiner respectfully disagrees with Applicant. As commented above, Bard discloses, "flow control components that make-up the ICS system can include pumps, flow channels, manifolds, flow restrictor, valves, etc." (column 4, lines 36-37). Bard further discloses that for the plurality of individual detachable reaction units, one of the units may comprise a "pressure unit" (column 4, lines 53-64). Note that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the teachings of the prior art would have suggested to one having ordinary skill in the art at the time the invention was made that the pressure in the modular system is

controllable, as evidenced by the provision of "pressure units" and the synthesis of compounds under high-pressure or super-critical pressure conditions (column 3, lines 24-59). Furthermore, the provision of valves to the system is explicitly suggested and well known in the art for modifying the pressure of a reaction zone. Also, he specific placement of valves in the system (i.e., upstream or downstream, for varying the pressure in specific zones of the apparatus) depending on the intended use only involves ordinary skill in the art, since the rearrangement of parts is obvious.

10. Regarding the rejections made in claims 16, 17 and 19, in view of Ashmead as a secondary reference, applicants assert,

> "... the relevant independent claim (Claim 1) has been amended to recite a control module distinguishing over Bard and Ashmead. Thus, the suggested combination is not equivalent to the invention defined by the amended claims." (page 15, lines 11-14).

However, applicants' argument is moot in view of the new grounds of rejection, necessitated by amendment.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

* * *

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer A. Leung whose telephone number is 703-305-4951. The examiner can normally be reached on 8:30 am - 5:30 pm M-F, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Glenn A. Caldarola can be reached on 703-308-6824. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Jennifer A. Leung
October 6, 2003

Hien Tran

HIEN TRAN
PRIMARY EXAMINER